JUN 21 2000

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K001769.

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4253

Contact Person: Darlene J. Phillips

2. **Preparation date**

Date Special 510(k) prepared: 9 June 2000

3. **Device name**

Trade or Proprietary Name:
VITROS Chemistry Products CREA DT Slides
VITROS Chemistry Products DT Calibrator Kit

Common Name : Creatinine
Classification Name: Creatinine test system (21 CFR 862.1225).

4. **Predicate device**

The VITROS Chemistry Products CREA DT Slides (modified) and VITROS Chemistry Products DT Calibrator Kit are substantially equivalent to the VITROS Chemistry Product CREA DT Slides (current slide) and VITROS Chemistry Products DT Calibrator Kit .

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5. Device description

The VITROS DT60 Chemistry System uses VITROS Slides to perform discrete chemistry tests on body fluid specimens. All reactions necessary for a single quantitative measurement take place within the multilayered analytical element of a VITROS Slide.

The system is comprised of two main elements:

1. The VITROS Chemistry Products range of clinical chemistry products (in this case VITROS Chemistry Products CREA DT Slides (K820722), VITROS Chemistry Products NH_3 DT Slides (K820723), and VITROS Chemistry Products DT Calibrator Kit (K934071)), which are used with the VITROS DT60 Chemistry System to perform the VITROS CREA test.

2. The VITROS DT60 Chemistry System – instrumentation, which provides automated use of the chemistry slides. The VITROS DT60 Chemistry Systems were cleared for market by separate 510(k) pre-market notifications (K841503 and K912844).

The VITROS Chemistry System and Calibrators are dedicated specifically for use only with the VITROS Chemistry Products range of products.

6. Device intended use

VITROS CREA DT Slides
For *in vitro* diagnostic use only.
VITROS CREA DT Slides quantitatively measure creatinine (CREA) concentration in serum and plasma.

VITROS DT Calibrator Kit
For *in vitro* diagnostic use only.
VITROS Chemistry Products DT Calibrator Kit is specifically formulated for use as calibrators for ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl-, CO2, CREA, CRSC, Fe, GGT, GLU, HDLC, K+, LAC, LDH, LDLC, LIPA, Mg, Na+, NH3, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

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7. Comparison to predicate device

The VITROS Chemistry Product CREA DT Slides (modified) and VITROS Chemistry Products DT Calibrator Kit are substantially equivalent to VITROS Chemistry Product CREA DT Slides (current) which was cleared by the FDA (K820722) for *in vitro* diagnostic use.

Table 1 lists the characteristics of the tests performed using the VITROS CREA DT Slides (modified) and the VITROS CREA DT Slides (current).

Table 1 List of Assay Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS CREA DT Slide (Modified)	Predicate Device VITROS CREA DT Slide (Current)
Slide Reactive Ingredient: Creatinine iminohydrolase (E.C. 3.5.4.21)	Biological Source: Bacillus species	Biological Source: Flavobacterium filamentosum
Sample volume	No change	10 µL
Sample type	No change	Serum or plasma
Assay Range Serum, Plasma	No change	0.01 - 15.0 mg/dL
Basic principle	No change	Dry, multilayered slide utilizing reflectance spectrophotometry
Instrumentation	No change	VITROS DT60 Chemistry Systems
Incubation time and temperature	No change	5 minutes at 37°C

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8. Conclusions The information presented in the pre-market notification demonstrate that the performance of the VITROS CREA DT Slide (modified) for use with serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient samples and quality control samples with measured creatinine values spanning the assay range.

The information presented in the premarket notification provide a reasonable assurance that the VITROS CREA DT Slide (modified) is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 21 2000

Ms. Darlene J. Phillips
Regulatory Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K001769
Trade Name: VITROS Chemistry Products CREA DT Slides
VITROS Chemistry Products Calibrator Kit
Regulatory Class: II
Product Code: CGX, JIS
Dated: June 09, 2000
Received: June 12, 2000

Dear Ms. Phillips:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K001769

Device Name:

VITROS Chemistry Products CREA DT Slides
VITROS Chemistry Products DT Calibrator Kit

Intended Use:

VITROS Chemistry Products CREA DT Slides
For *in vitro* diagnostic use only.

VITROS CREA DT Slides quantitatively measure creatinine (CREA) concentration in serum and plasma.

VITROS Chemistry Products DT Calibrator Kit
For *in vitro* diagnostic use only.

VITROS Chemistry Products DT Calibrator Kit is specifically formulated for use as calibrators for ALB, ALKP, ALT, AMYL, AST, TBIL, NBIL, BUN/UREA, Ca, CHOL, CK, Cl-, CO2, CREA, CRSC, Fe, GGT, GLU, HDLC, K+, LAC, LDH, LDLC, LIPA, Mg, Na+, NH3, PHOS, TP, TRIG, urCR, and URIC on VITROS DT Chemistry Systems.

Summary and Explanation of Test:

Creatinine is a waste product excreted by the kidneys. Blood creatinine levels generally do not increase until renal function is substantially impaired. Simultaneous analysis of urea nitrogen (BUN/UREA) and creatinine levels are clinically helpful because creatinine levels are not effected by a high protein diet.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Lab
510(k) Number K001769

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)